



THE ASSOCIATION FOR
**DRESSINGS
& SAUCES**

5775 PEACHTREE-DUNWOODY ROAD • BUILDING G, SUITE 500 • ATLANTA, GEORGIA 30342 • (404) 252-3663 • FAX: (404) 252-0774
E-mail: ads@kellencompany.com • Web: www.dressings-sauces.org

January 14, 2005

Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, Maryland 20852

**Re: Reopening of the Comment Period – Food Labeling: Health
Claims, General Requirements
FDA Docket Nos. 1994P-0390 and 1995P-0241**

These comments are submitted by the Association for Dressings and Sauces (“ADS”) in response to FDA’s reopening of the comment period for the proposed rule, “Food Labeling: Nutrient Content Claims, General Principles; Health Claims, General Requirements and Other Specific Requirements for Individual Health Claims,” which was initially published in 1995. ADS’ comments address the 10 percent nutrient contribution requirement for health claims, set forth at 21 C.F.R. § 101.14(e)(6), and the disqualifying level for total fat on a 50 g basis set forth at 21 C.F.R. § 101.14(a)(4). ADS is an international trade association of manufacturers of retail and foodservice dressings for salads, mayonnaise, and other condiments, and the companies that supply these manufacturers. The 178 member companies of ADS have a strong interest in the availability of health claims for dressings for salads, and appreciate FDA’s reopening of the comment period on the important issue of facilitating dissemination of health information through food labeling to help consumers understand the relationship between diet and health.

As an initial matter, ADS believes that the 10 percent nutrient contribution requirement and total fat disqualifying level would not withstand First Amendment scrutiny if challenged. For this reason, ADS asserts that these requirements should be eliminated in their entirety. Failing that, however, ADS urges FDA to amend the agency’s health claims regulations to exempt dressings for salad from these requirements. Because ADS is aware that many commenters representing a broad spectrum of industry will address the First Amendment concerns surrounding these requirements, ADS’ comments are focused on the particular scientific and public health policy issues relating to dressings for salad, which justify the exemption of these foods.

I. Dressings for Salad Should Be Excluded from the 10 Percent Nutrient Contribution Requirement

The 10 percent nutrient contribution requirement for health claims allows such claims on conventional foods only if the food contains 10 percent or more of the Reference Daily Intake (“RDI”) or

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the Daily Reference Value ("DRV") for vitamin A, vitamin C, iron, calcium, protein, or fiber per reference amount customarily consumed ("RACC"), prior to any fortification, unless an exception is expressly granted. FDA has acknowledged that dressings for salad generally cannot satisfy this requirement, and has waived it for certain claims in recognition of the valuable contribution such dressings make to the diet. *See* Health Claims: Plant Sterol/Stanol Esters and Risk of Coronary Heart Disease ("CHD"), 21 C.F.R. § 101.83(c)(2)(iii)(D); Letter Responding to Health Claim Petition Dated August 28, 2003: Monounsaturated Fatty Acids from Olive Oil and Coronary Heart Disease, November 1, 2004, at 16 ("MUFAs from olive oil qualified health claim letter of enforcement discretion").

FDA has not been consistent in its imposition of the 10 percent nutrient contribution requirement for dressings for salad, however. The agency refused to waive this requirement for its recently-authorized qualified health claim for certain omega-3 fatty acids and reduced risk of CHD, on grounds that conflict with the approach taken by FDA regarding the plant sterol/stanol esters health claim. *See* Letter Responding to Health Claim Petition Dated June 23, 2003 (Wellness Petition): Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease, September 8, 2004 ("omega-3/CHD qualified health claim").¹ This discrepancy reveals the need for FDA to establish a uniform approach to the application of this requirement to dressings for salads.

ADS agrees with FDA's recognition that "the 10 percent nutrient contribution requirement may have had the unintended effect of prohibiting health claims on certain foods that could be beneficial to consumers and help them to maintain a balanced and healthful diet." 60 Fed. Reg. 66206, 66212 (December 21, 1995) ("Proposed Rule"). That result is particularly detrimental in light of the agency's recent Consumer Health Information for Better Nutrition Initiative, which FDA explains is intended "to make available more and better information about conventional foods and dietary supplements to help American consumers improve their health and decrease their risk of contracting diseases by making sound dietary decisions" and to "increase competition by product developers in support of healthier diets." 69 Fed. Reg. 24541, 24542 (May 4, 2004). Where the 10 percent nutrient contribution requirement functions to preclude entire classes of food from bearing health claims, as is the case for dressings for salad, manufacturers of those foods have little incentive to formulate their products in a more healthful manner. Manufacturers of dressings for salad have been and continue to be committed to modifying the nutrient profiles of their products to appeal to consumers with different dietary needs. For example, the industry produces products ranging from fat-free to reduced-fat to regular dressings and formulates many dressings with healthful olive and canola oils as well as modified carbohydrate varieties. While the dressing industry has responded to evolving science about the relationship between diet and health in formulating its products, it is hampered in its ability to inform consumers about the health significance of these formulations because of current regulations, such as the 10 percent nutrient contribution requirement.

¹ ADS has submitted a letter to FDA requesting reconsideration of its refusal to waive the 10 percent nutrient contribution requirement and total fat disqualifying level on a 50 g basis for the omega-3/CHD qualified health claim ("ADS Letter on Omega-3/CHD Claim"), a copy of which is attached hereto as Attachment A.

A. Dressings for Salad Should Be Excluded from the 10 Percent Nutrient Contribution Requirement for the Reasons FDA Proposes to Exclude Fruits, Vegetables, and Certain Other Foods

FDA's rationale for its proposal to exempt fruits and vegetables from the 10 percent nutrient contribution requirement applies in large measure to dressings for salads, which by their very nature are consumed with vegetable salads.² FDA noted that its primary goals in establishing this requirement were to "preclude foods of little or no nutritional value from bearing health claims and, at the same time, to enhance the likelihood of consumers constructing overall daily diets that conform to dietary guidelines," and recognized that precluding certain fruits, vegetables, and other products from bearing health claims because of this requirement is contrary to that goal. 60 Fed. Reg. at 66213. In reaching this determination, FDA acknowledged that current dietary guidance promotes consumption of these foods. *Id.* The agency stated further:

Moreover, diets high in fruits, vegetables, and grain products have been associated with various specific health benefits, including lower occurrence of coronary heart disease and of some cancers and therefore, are exactly the types of foods that should be included in the diet to reduce the risk of specific diet-related diseases. Precluding such foods from bearing health claims could confuse consumers and undermine the utility of health claims.

Id. (references omitted). Because dressings for salad are virtually never eaten alone but rather are consumed with vegetable and/or fruit salads, FDA's proposed exemption of vegetables and fruit from the 10 percent nutrient contribution requirement should be extended to dressings for salads as well.

In the context of the overall diet, dressings for salad serve as accompaniments that enhance consumer enjoyment of nutrient-rich mixed vegetable salads. A prominent pillar of current dietary guidelines is the recommendation to increase consumption of a variety of fruits and vegetables. The 2000 Dietary Guidelines for Americans encourage consumers to "choose a variety of fruits and vegetables daily," and the Food Guide Pyramid recommends consumption of three to five servings of vegetables a day. The 2005 Dietary Guidelines Advisory Committee Report indicates that the newly revised dietary guidelines will maintain the recommendation that consumers increase their daily intakes of fruits and vegetables. Additionally, last year FDA announced its collaboration with the National Cancer Institute, to support the dietary guidance message in food labeling, "*Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases.*"

Considering the role a food plays in the dietary context is important in evaluating the applicability of the 10 percent nutrient contribution requirement. Given that dressings for salad are consumed with vegetable and/or fruit salads, an appropriate assessment of the nutrient contribution of this food must take into consideration the nutritive value of the salad consumed with it. FDA made such an assessment in the context of the plant sterol/stanol esters health claim, and concluded that an exemption for dressings for salad was warranted. In the preamble to the final rule for that claim, FDA explained:

² FDA readily will be able to distinguish dressings for salad from other types of dressings or spreads by their labeling, marketing, and placement on store shelves, and can therefore apply different health claim criteria to these types of dressings.

The agency believes that the value of health claims will not be trivialized or compromised by their use on dressings for salad because dressings for salad are often consumed with foods rich in nutrients and fiber. Salads, for example, are usually rich in vegetables that provide important nutrients at significant levels, e.g., tomatoes – vitamins A and C; carrots – vitamin A; spinach – vitamin A and calcium.

65 Fed. Reg. 54686, 54711 (Sept. 8, 2000). This rationale is not limited to the context of the plant sterol/stanol esters claim, but rather applies to dressings for salad in every instance. Accordingly, there is no reason why this should not be FDA's approach to dressings for salad as a general rule. Dressings for salad should be exempted, by regulation, from the application of the 10 percent nutrient contribution requirement. Allowing health claims on dressings for salad will help consumers maintain healthy dietary practices by encouraging consumption of the dressings along with vegetable salads, in conformance with national dietary guidelines.

B. FDA Should Not Limit the Exemption for Fruits and Vegetables to Products Comprised Solely of Fruits and Vegetables

In the Proposed Rule, FDA proposed to limit the exemption for fruit and vegetable products to those products comprised solely of fruits and vegetables. FDA planned to impose this limitation out of concern that permitting health claims on fruit and vegetable products that do not meet the 10 percent nutrient contribution requirement, but that contain ingredients that may raise the level of other nutrients such as fat, cholesterol, and sodium, would be inconsistent with the purpose of the health claim and incompatible with current dietary guidelines. 60 Fed. Reg. at 66214. FDA's concern is misplaced, and conflates the role of the 10 percent nutrient contribution requirement with the function of the disqualifying levels codified at 21 C.F.R. § 101.14(e)(3). The disqualifying levels purport to ensure that foods do not bear health claims where the amount of fat, cholesterol, and sodium exceeds levels compatible with healthy dietary practices.³ The present regulatory scheme does not require this factor to be considered with respect to the 10 percent nutrient contribution requirement as well.

Moreover, FDA's proposed approach is unsubstantiated by scientific evidence. Evidence abounds concerning the health benefits of a diet rich in fruits and vegetables, and it has not been shown that these benefits are undermined when fruits and vegetables are consumed with other ingredients. To the contrary, one clinical study⁴ has demonstrated that the nutritional benefits of salad are actually enhanced when consumed with fat-containing dressing.

³ ADS does not agree with the general application of disqualifying levels, and considers them an arbitrary and inappropriate means of precluding health claims on certain foods, and in violation of established First Amendment principles that favor a case-by-case approach to justify government speech restrictions. In particular, ADS argues against the application of the total fat disqualifying level on a per 50 g basis to dressings for salad in these comments, below, and in the ADS Letter on Omega-3/CHD Claim.

⁴ Brown, M., et al., *Carotenoid bioavailability is higher from salads ingested with full-fat than with fat-reduced salad dressings as measured with electrochemical detection*, 80 Am. J. Clin. Nutr. 396 (2004) ("Carotenoid Bioavailability Study"), a copy of which is attached to the ADS Letter on Omega-3/CHD Claim submitted with these comments.

The Carotenoid Bioavailability Study and related research indicates that the fatty acid composition of traditional full-fat dressings for salads contributes significantly to vitamin nutrition. As acknowledged in the 2005 Dietary Guidelines Advisory Committee Report, fats serve as a carrier for the absorption of the fat-soluble vitamins A, D, E, and K, and carotenoids. The Carotenoid Bioavailability Study demonstrates that carotenoid bioavailability is substantially greater from salads ingested with full-fat than with fat-reduced salad dressings, and is somewhat greater with fat-reduced dressings than with fat-free dressings. The study set out to determine the amount of fat needed to absorb carotenoids in plant matrices. Subjects consumed a test salad consisting of 48 g fresh spinach, 48 g romaine lettuce, 66 g raw shredded carrots, and 85 g raw cherry tomatoes, along with a 60-g serving of either fat-free, reduced-fat, or full-fat salad dressing containing 0, 6, or 28 g fat, respectively. Blood samples were collected hourly from 0 to 12 h after consumption, and the appearance of α -carotene, β -carotene, and lycopene in chylomicrons was analyzed. The study results showed essentially that no absorption of carotenoids occurred when salads with fat-free dressing were consumed, whereas some absorption occurred after ingestion of salads with reduced-fat dressing, and substantially greater absorption of carotenoids occurred when the salads were consumed with full-fat dressing. The Carotenoid Bioavailability Study concluded that dietary fat may be particularly essential to the bioavailability of fat-soluble carotenoids in vegetables to promote their release from the plant matrix and their incorporation into mixed micelles.

Ingestion of the test salad with the fat-free dressing is essentially comparable to ingestion of the salad vegetables alone for purposes of carotenoid bioavailability, because carotenoids are fat-soluble vitamins. Accordingly, the results of the Carotenoid Bioavailability Study demonstrate that vegetables ingested with at least some fat yield a greater carotenoid benefit than the vegetables alone. FDA has recognized the public health benefit of carotenoids supplied by fruits and vegetables (e.g., β -carotene) in its regulations authorizing health claims for fruits and vegetables and cancer. 21 C.F.R. § 101.78(c)(2)(ii)(C). This study indicates that the health benefits derived from vegetables are substantially enhanced, rather than diminished, when the vegetables are ingested with fat-containing dressings for salad.

Accordingly, FDA's proposal to limit the fruit and vegetable exemption from the 10 percent nutrient contribution requirement to products comprised solely of fruits and vegetables is unjustified in light of the scientific evidence, which in fact supports the health-promoting role of dressings for salad in the diet in a manner consistent with current dietary guidelines and public health policy.

For these reasons, FDA should extend the proposed exemption from the 10 percent nutrient contribution requirement to include dressings for salad. As explained in the preamble to the final health claim regulations, this requirement was intended to address concerns about "foods like sugars, soft drinks, and sweet desserts." 58 Fed. Reg. 2478, 2522 (Jan. 6, 1993). Indeed, the nickname "jelly bean rule" reveals that this requirement is targeted towards candy and other snack foods that are consumed in a manner that makes little or no positive contribution to the diet. Dressings for salad, on the other hand, make a substantial positive dietary contribution by enhancing consumer enjoyment of vegetable salads and therefore encouraging their consumption, thus increasing consumption of vegetables that contain many of the nutrients addressed in the 10 percent nutrient contribution requirement. Consequently, dressings for salad help consumers maintain healthy dietary practices in conformance with national dietary guidelines. Dressings for salad should therefore be exempted from the 10 percent nutrient contribution requirement for health claims.

II. Disclosure, Rather than the Disqualifying Level for Total Fat on a 50 g Basis, Should Be the Approach for Dressings for Salad

The general requirements for health claims in 21 C.F.R. § 101.14 include a disqualifying level for total fat of 13 g per RACC, per label serving size, and for foods with reference amounts customarily consumed of 30 g or less or 2 tablespoons or less, per 50 g. Because the RACC for dressings for salad is 2 tablespoons, this rule would impose a disqualifying level of 13 g total fat per 50 g. FDA has recognized that on a 50 g basis, the total fat disqualifying level generally precludes many dressings for salad from bearing health claims, and has required disclosure rather than disqualification to permit such dressings to bear the plant sterol/stanol esters health claim and the MUFAs from olive oil qualified health claim. See 21 C.F.R. § 101.83(c)(2)(iii)(C); MUFAs from olive oil qualified health claim letter of enforcement discretion at 14. FDA's approach has not been consistent, however, and for the omega-3/CHD qualified health claim the agency declined to exempt dressings for salad from the total fat disqualifying level per 50 g.⁵

FDA's imposition of the total fat disqualifying level on a 50 g basis on dressings for salads is unjustified from a public health perspective and fails to recognize the actual role of such dressings in the diet. Viewing dressings for salad as foods with small serving sizes does not reflect the real-world consumption patterns for these foods. Rather, they should be considered as part of a larger meal – the dressed salad, which has a RACC of 100 g. When analyzed in their proper context in the diet, dressings for salad are distinguishable from those foods with small serving sizes that are concentrated sources of fat. While FDA has expressed concern that foods with small serving sizes may be consumed more frequently than once a day, that is not likely to be the case for dressings for salad, which will be consumed as part of a larger meal rather than on their own, and therefore the natural mechanisms of human satiety will function to limit consumption. If these dressings are consumed more than once a day, it will be in conjunction with a vegetable salad.

Consumers choosing to expend a portion of their dietary fat allotment (Daily Value) through dressings that are consumed with a vegetable salad would gain substantial nutritional benefits compared with alternatives, and would be pursuing a dietary pattern that comports with current dietary guidelines. Moreover, as explained in detail above, the Carotenoid Bioavailability Study demonstrated that the fat in dressings for salad serves a nutritional purpose by substantially enhancing the bioavailability of carotenoids from salad vegetables. Finally, it is significant that the fat composition of dressings for salad is generally consistent with dietary guidelines on saturated fat and cholesterol, as many dressings are formulated with olive or canola oils. The majority of dressings for salad do not contain *trans* fat because liquid vegetable oils that are not partially hydrogenated are a primary ingredient in salad dressings.

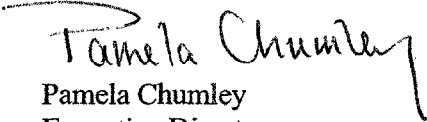
FDA's inconsistent approach toward the imposition of the total fat disqualifying level on a 50 g basis to dressings for salad is unjustified from a public health perspective and in light of the scientific evidence, provides little incentive for manufacturers of dressings for salad to develop even healthier formulations of their products, and creates a "chilling effect" on speech by discouraging manufacturers from petitioning the agency for health claims because the end result is too uncertain. To

⁵ See ADS Letter on Omega-3/CHD Claim, attached, for ADS' detailed argument as to why FDA should reverse this determination.

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remedy this, FDA should amend the health claim general requirements to require disclosure rather than disqualification for dressings for salad that exceed the total fat disqualifying level on a 50 g basis.

Respectfully submitted,



Pamela Chumley

Pamela Chumley
Executive Director

Attachment



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DRESSINGS
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5775 PEACHTREE-DUNWOODY ROAD • BUILDING G, SUITE 500 • ATLANTA, GEORGIA 30342 • (404) 252-3663 • FAX: (404) 252-0774
E-mail: ads@kellencompany.com • Web: www.dressings-sauces.org

December 15, 2004

Mr. William K. Hubbard
Associate Commissioner for Policy and Planning
Food and Drug Administration
5630 Fishers Lane
Room 14101
Rockville, MD 20852

Re: Eligibility of Dressings for Salad to Bear the Qualified Health
Claim Regarding Certain Omega-3 Fatty Acids and Reduced Risk
of Coronary Heart Disease

Dear Mr. Hubbard:

This letter is submitted by the Association for Dressings and Sauces ("ADS") to request that the Food and Drug Administration ("FDA") exercise enforcement discretion to permit certain dressings for salad that exceed the total fat disqualifying level per 50 g, and do not in themselves meet the ten percent minimum nutrient content requirement, to bear the qualified health claim for certain omega-3 fatty acids and reduced risk of coronary heart disease ("omega-3/CHD qualified health claim"). ADS is an international trade association of manufacturers of retail and foodservice salad dressing, mayonnaise, and other condiments, and the companies that supply these manufacturers. With 178 member companies, ADS has a strong interest in the availability of the omega-3 qualified health claim for certain dressings for salad.

ADS requests that FDA permit the omega-3/CHD qualified health claim for certain dressings for salad for which consumption supports dietary patterns that are consistent with national dietary guidelines with respect to fruit and vegetable intake and promotes a favorable fatty acid profile in the diet. ADS' request is rooted in the recognition that dressings for salad are virtually never eaten alone. By their very nature, they are consumed with salads. In its letters responding to the health claim petitions, "Omega-3 Fatty Acids and Reduced Risk of Coronary Heart Disease" ("Letter Responses"), FDA addressed spreads, dressings for salad, and other mayonnaise-based dressings uniformly. This approach overlooked the specialized role of

dressings for salad in the diet – that they are nearly always eaten as part of a vegetable salad and typically supply most or all of the fat in the salad.¹ Further, most salad dressings are made from oils whose fatty acid profiles comport with current dietary guidelines relating to fat. For example, the majority of dressings for salad do not contain *trans* fat because liquid vegetable oils that are not partially hydrogenated are a primary ingredient in salad dressings. Further, many salad dressings use olive oil, which is high in monounsaturated fatty acids, and canola oil, which is high in both mono- and polyunsaturated fatty acids that are recommended in place of saturated fats. These facts provide strong support for the use of the omega-3/CHD qualified claim on grounds that are consistent with FDA policy with respect to CHD claims concerning plant sterol/stanol esters, olive oil, walnuts and other type nuts. As detailed below, allowing the omega-3/CHD qualified claim on dressings for salad is consistent with national dietary guidelines, and would assist consumers in maintaining healthy dietary practices.

I. The Fatty Acid Profile of Omega-3-Containing Dressings for Salad Would Promote Diets Consistent with Dietary Guidelines

As an initial matter, ADS notes that it is seeking the omega-3/CHD qualified health claim for dressings for salad whose fat composition is consistent with dietary guidelines on saturated fat and cholesterol. Under the terms of the FDA Letter Response, dressings that would qualify for the claim would not exceed the disqualifying levels for saturated fat and cholesterol, and generally would contain no significant level of *trans* fatty acid. When formulated with omega-3 fatty acids, such dressings also would promote a healthy balance of omega-6 and omega-3 fatty acids in the diet. Current estimates of average intake indicate that the ratio of omega-6 to omega-3 fatty acids in the diet is approximately 9.8:1, a gross distortion in relation to the 2.3:1 and 4:1 ratios recommended for meeting human nutritional needs. See Kris-Etherton, *et al.*, *Polyunsaturated fatty acids in the food chain in the United States*, 71 Am. J. Clin. Nutr. 179 (2000); see also Simopoulos, A., *Essential fatty acids in health and chronic disease*, 70 Am. J. Clin. Nutr. 560S (1999). Dressings formulated with omega-3 fatty acids would be helpful in promoting a favorable balance of these fatty acids in the diet, particularly since the amount of added omega-3 fatty acids in the dressing typically would operate to displace omega-6 fatty acids in the formulation.

Allowing the omega-3/CHD qualified health claim on omega-3-containing dressings for salad would assist consumers in maintaining healthy dietary practices with respect to the overall balance of fatty acids in the diet.

¹ In exercising its enforcement discretion with respect to the omega-3/CHD qualified health claim, FDA readily will be able to distinguish dressings for salad from other types of dressings or spreads by their labeling, marketing, and placement on store shelves, and can therefore apply different criteria to these types of dressings.

II. Omega-3-Containing Dressings for Salad Support Food Consumption Patterns Consistent with Dietary Guidelines

It is well established that authorized health claims are intended to assist consumers in maintaining healthy dietary practices and account for the role the food plays in the context of the total daily diet. Indeed, in the portion of the preamble to FDA's final health claims regulations discussing the ten percent minimum nutrient content requirement, FDA notes that "Congress intended that FDA establish provisions of health claims regulations by considering the role of the nutrients in food in a way that will enhance the chances of consumers constructing total daily diets that meet dietary guidelines." 58 Fed. Reg. 2478, 2521 (Jan. 6, 1993).

In the context of the overall diet, dressings for salad serve as accompaniments that enhance consumer enjoyment of nutrient-rich mixed vegetable salads. A prominent pillar of current dietary guidelines is the recommendation to increase consumption of a variety of fruits and vegetables. The 2000 Dietary Guidelines for Americans encourage consumers to "choose a variety of fruits and vegetables daily," and the Food Guide Pyramid recommends consumption of three to five servings of vegetables a day. The 2005 Dietary Guidelines Advisory Committee Report indicates that revised next year's revised dietary guidelines will maintain the recommendation that consumers increase their daily intakes of fruits and vegetables. Additionally, last year FDA announced its collaboration with the National Cancer Institute, to support the dietary guidance message in food labeling, *"Diets rich in fruits and vegetables may reduce the risk of some types of cancer and other chronic diseases."*

FDA acknowledged in its Letter Responses that health claims on foods such as dressings would promote their consumption. With respect to dressings for salad, the corollary is that promoting their consumption necessarily promotes consumption of salads (vegetables) as well. Consequently, promoting consumption of omega-3-containing dressings for salad would help consumers maintain healthy dietary practices by promoting consumption of vegetables, in accordance with national dietary guidance. While allowing the qualified health claim on low-fat or fat-free dressings for salad may also promote consumption of vegetables, the benefits of added omega-3 fatty acids would be promoted only to the more limited segment of consumers who choose low fat or fat free dressings. Consumers preferring more traditional full-fat dressings would be excluded from these benefits. As discussed in detail below, consumers of full-fat dressings appear to benefit from greater carotenoid absorption from salads, and may prefer such products on health or other grounds. It is not clear, from the current state of scientific evidence, whether consumers would obtain a net health benefit from consuming dressings that are low in total fat but fail to deliver the maximum amount of carotenoids from the salad.

Considering the role a food plays in the dietary context is important in evaluating the applicability of the ten percent minimum nutrient content claim requirement. In its Letter Responses, FDA took the position based on the nutrient profile of dressings for salad and mayonnaise-type dressings by themselves, that the "ten percent" standard would not be satisfied,

and permitting the omega-3/CHD claim “would be inconsistent with the principle of health claims, i.e., that health claims should be used on foods that help maintain healthy dietary practices.”² Given that dressings for salad are consumed with vegetable salads, a more appropriate assessment of the nutrient contribution of this food must take into consideration the nutritive value of the salad consumed with it.

ADS’ request that FDA allow the omega-3/CHD claim for certain dressings for salads is consistent with the FDA policy established for the plant sterol/stanol esters health claim. In that context, the agency recognized the public health benefits that would be gained by waiving the total fat disqualifying level and ten percent minimum nutrient content requirement for dressings for salad. In the preamble to the final rule for that claim, FDA acknowledged that such dressings are consumed with salad vegetables, and explained:

The agency believes that the value of health claims will not be trivialized or compromised by their use on dressings for salad because dressings for salad are often consumed with foods rich in nutrients and fiber. Salads, for example, are usually rich in vegetables that provide important nutrients at significant levels, e.g., tomatoes – vitamins A and C; carrots – vitamin A; spinach – vitamin A and calcium.

65 Fed. Reg. 54686, 54711 (Sept. 8, 2000). The same analysis applies to the omega-3/CHD qualified health claim. As omega-3-containing dressings for salad are generally consumed with vegetable salads, allowing health claims on this food would help consumers maintain healthy dietary practices by encouraging consumption of the dressings along with vegetables in conformance with national dietary guidelines.

Dietary guidelines are not undermined by allowing the omega-3/CHD qualified health claim on omega-3-containing dressings for salad that exceed the total fat disqualifying level per 50 g. Again, the context of consumption must be considered. Viewing dressings for salad as foods with small serving sizes does not reflect the actual consumption patterns for these foods. Rather, they should be considered as part of a larger meal – the dressed salad, which has a RACC of 100 g. When analyzed in their proper context in the diet, dressings for salad are

² FDA also asserted that dressings for salad and mayonnaise-type dressings “are the type of foods that FDA had in mind when it required the 10 percent minimum nutrient content as a general requirement for health claims because nutritional values are low while fat and calories are high.” ADS respectfully disagrees that this requirement was intended to preclude foods such as dressings for salad from bearing health claims. The discussion of this requirement in the preamble to the final health claim regulations refers to “foods like sugars, soft drinks, and sweet desserts.” 58 Fed. Reg. 2478, 2522 (Jan. 6, 1993). Indeed, the nickname “jelly bean rule” reveals that this requirement is targeted towards candy and other snack foods that are consumed in a manner that makes little or no positive contribution to the diet.

distinguishable from those foods with small serving sizes that are concentrated sources of fat. FDA stated in its Letter Responses that foods with small serving sizes may be consumed more frequently than once a day. That is not likely to be the case for dressings for salad, which will be consumed as part of a larger meal rather than on their own, and therefore the natural mechanisms of human satiety will function to limit consumption. If these dressings are consumed more than once a day, it will be in conjunction with a vegetable salad. Consumers choosing to expend a portion of their dietary fat allotment (Daily Value) through dressings for salads that are formulated with omega-fatty acids would gain substantial nutritional benefits compared with alternatives.

III. The Fat Content of Dressings for Salad Contributes Nutritional Benefits

The findings of the Carotenoid Bioavailability Study³ and related research indicate that the fatty acid composition of traditional full-fat dressings for salads contributes significantly to vitamin nutrition. As acknowledged in the 2005 Dietary Guidelines Advisory Committee Report, fats serve as a carrier for the absorption of the fat-soluble vitamins A, D, E, and K, and carotenoids. The Carotenoid Bioavailability Study, recently published in the American Journal of Clinical Nutrition, demonstrates that carotenoid bioavailability is substantially greater from salads ingested with full-fat than with fat-reduced salad dressings. The study set out to determine the amount of fat needed to absorb carotenoids in plant matrices. Subjects consumed a test salad consisting of 48 g fresh spinach, 48 g romaine lettuce, 66 g raw shredded carrots, and 85 g raw cherry tomatoes, along with a 60-g serving of either fat-free, reduced-fat, or full-fat salad dressing containing 0, 6, or 28 g fat, respectively. Blood samples were collected hourly from 0 to 12 h after consumption, and the appearance of α -carotene, β -carotene, and lycopene in chylomicrons was analyzed. The study results showed essentially that no absorption of carotenoids occurred when salads with fat-free dressing were consumed, whereas some absorption occurred after ingestion of salads with reduced-fat dressing, and substantially greater absorption of carotenoids occurred when the salads were consumed with full-fat dressing.

The Carotenoid Bioavailability Study concluded that, in the absence of other sources of fat, the use of fat-free or reduced fat salad dressings can limit the absorption of the carotenoids abundant in fresh salads, and that dietary fat may be particularly essential to the bioavailability of fat-soluble carotenoids in vegetables to promote their release from the plant matrix and their incorporation into mixed micelles. While the study acknowledged that salads may be consumed with other accompaniments that contribute dietary fat, it also cited an analysis by Krebs-Smith, *et al.*, which, using data from the 1985 Continuing Survey of Food Intakes by Individuals, identified salad dressings as the major source of fat in women's diets.⁴ Accordingly, the Study's

³ Brown, M., *et al.*, *Carotenoid bioavailability is higher from salads ingested with full-fat than with fat-reduced salad dressings as measured with electrochemical detection*, 80 Am. J. Clin. Nutr. 396 (2004) ("Carotenoid Bioavailability Study"), attached hereto as Attachment A.

⁴ Krebs-Smith, S. M., *et al.*, *Food sources of energy, macronutrients, cholesterol, and fiber in diets of women*, 101 J. Am. Diet. Assoc. 168 (1992).

authors expressed concern that, “[b]y choosing reduced-fat or fat-free salad dressings, consumers could potentially compromise their exposure to the putative bioactivity of those carotenoids in preventing heart disease, cancer, and other chronic diseases.” Carotenoid Bioavailability Study at 397. In the FDA regulations authorizing health claims for fruits and vegetables and cancer, the agency has recognized the public health benefit of carotenoids supplied by fruits and vegetables (e.g., β -carotene). 21 C.F.R. § 101.78(c)(2)(ii)(C). This study indicates that the fat contributed to the diet from traditional full-fat dressings for salad provides significant benefits with respect to vitamin nutrition.

IV. The Fat Content of Dressings for Salad is an Appropriate Vehicle for Fat-Soluble Omega-3 Fatty Acids

For FDA policies aimed at promoting dietary consumption of omega-3 fatty acids to be effective, established consumer food and fat consumption preferences must be considered. The fat-soluble character of omega-3 fatty acids makes fat-containing foods desirable vehicles for delivery of these ingredients. In the preamble to FDA’s interim final rule authorizing the plant sterol/stanol health claim, FDA recognized the public health benefit to be gained in authorizing the CHD health claim for fat-containing foods, including dressings for salad. “Spreads and dressings for salad ... are appropriate vehicles for plant sterol/stanol esters because such substances are soluble in these fat-based foods.” 65 Fed. Reg. 54686, 54709 (September 8, 2000). The same rationale supports the omega-3/CHD health claim for dressings for salad.

FDA took a comparable approach in its recent authorization of a qualified health claim for olive oil and olive oil-containing foods and reduced risk of CHD. As with the omega-3/CHD qualified health claim, the substance that is responsible for the claimed CHD benefit – olive oil – consists of fatty acids. FDA recognized the adverse public health implications that would result from applying the disqualifying level for total fat to products containing olive oil, including dressings for salad, by limiting the actual food choices available to consumers that could qualify for the claim.

ADS’ proposal for omega-3 fatty acid/CHD claims is consistent with the FDA policy applied to olive oil products. By adopting analogous policies for the olive oil/CHD and omega-3 fatty acid/CHD health claims, the agency can avert potentially illogical outcomes for labeling dressing products in the case that a dressing was formulated to contain both olive oil and omega-3 fatty acids. In addition, inconsistent policies would discourage manufacturers of olive oil-containing dressings to enhance the nutritional value further through the addition of omega-3 fatty acids to their product formulations.

In sum, allowing the use of omega-3 fatty acid/CHD qualified health claims for dressings for salad – without regard to the total fat disqualifying level per 50 g and ten percent minimum nutrient content requirement – would be consistent with FDA policies concerning other CHD health claims for substances that are fat soluble and/or are comprised of fatty acids, and would promote compliance with national dietary guidelines with respect to fruit and vegetable consumption and dietary fat consumption. The policy would assist consumers in maintaining healthy dietary practices by encouraging increased vegetable consumption, promoting absorption

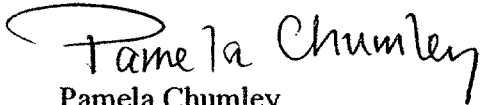
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and bioavailability of the carotenoids supplied by salads, and by promoting consumption of a healthy balance of fatty acids in the diet.

Respectfully submitted,

A handwritten signature in cursive script that reads "Pamela Chumley". The signature is written in dark ink and is positioned above the printed name and title.

Pamela Chumley
Executive Director

Attachment